

**Appendix A. Letter to physicians** Flesch-Kincaid Grade Level = 12.6

Dear Dr. \_\_\_\_\_

The Agency for Toxic Substances and Disease Registry (ATSDR), an agency of the US Public Health Service, plans to offer the BeLPT blood test to people in the Elmore, Ohio, area. We can test up to 200 people who want to find out if their immune systems have been sensitized to beryllium. We would appreciate your assistance in notifying your sarcoidosis patients about this opportunity for testing.

Because sarcoidosis and chronic beryllium disease (CBD) are similar clinically, some patients diagnosed with "sarcoidosis" may actually have chronic beryllium disease (CBD). For example, sarcoidosis was the original diagnosis given to a local beryllium worker's wife:

*"Nonoccupational beryllium disease masquerading as sarcoidosis: identification by blood lymphocyte proliferative response to beryllium. Am Rev Respir Dis. 1992 May; 145(5): 1212-4."*

There will be no cost to your patient for these blood tests. People tested will receive copies of their test results. If your patient gives us permission, we will also send a copy to you.

We have enclosed copies of a factsheet that you can give to your sarcoidosis patients. If you have any questions, you can call the ATSDR toll free line (1-888-422-8737) and ask for me. Or, if you prefer, my direct line is 1-404-498-0565.

During May 2006, your sarcoidosis patients can call 1-866-577-4258 to request the test. This toll free line will be answered between the hours of 8 am - 8 pm (EST), Monday through Friday from May 1, 2006 through May 31, 2006.

Thank you,

Dan Middleton, MD, MPH

Enclosure: factsheet

## **Appendix B. Letter to Nearby Residents**

Flesch-Kincaid Grade Level = 8.8

Dear \_\_\_\_\_

The Agency for Toxic Substances and Disease Registry (ATSDR), an agency of the US Public Health Service, is offering to test people in your area for beryllium sensitivity. We can test up to 200 people who are concerned about their potential exposure to beryllium. A factsheet is enclosed with more information.

If you are interested, you can call us. We will ask you a few questions about where you live, your job, your age, and your health. You may choose not to answer any questions that you wish. These questions will take about 15 minutes.

If your information confirms that you are eligible, we will contact you to make an appointment. We will take about 2 tablespoons of blood from a vein in your arm. It usually takes less than 10 minutes to take this sample. Your blood will be tested to see if your immune system has been sensitized to beryllium. We will send your results to you. If you give us permission, we will also send a copy of your test results to your doctor.

During May 2006, you can call 1-866-577-4258 to volunteer for the test and find out if you are eligible. This line will be answered between the hours of 8 am - 8 pm (EST), Monday through Friday from June 1, 2006 through June 30, 2006.

Thank you,

Dan Middleton, MD, MPH

Enclosures: 1

## **Appendix C. Facts about Testing for Beryllium Sensitization**

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***Purpose***

This fact sheet describes a blood testing program being offered by the Agency for Toxic Substances and Disease Registry (ATSDR). This blood test is to determine if you have sensitivity to beryllium. ATSDR plans to offer this test to up to 200 people in the Elmore, Ohio area.

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***Beryllium  
Lymphocyte  
Proliferation  
Test (BeLPT)***

The name of the test being offered by ATSDR is the beryllium lymphocyte proliferation test (BeLPT). The BeLPT can identify people whose immune system is sensitive to beryllium, a kind of allergic response to beryllium from past exposure.

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***Who Will  
Be Offered  
the Test?***

The BeLPT will be offered to people who are concerned about past exposure to beryllium if they are household contacts of Brush Wellman workers, workers at machine shops that work with beryllium metals from Brush Wellman or their household contacts, live within 1 ¼ mile of the Brush Wellman facility, or have received a diagnosis of sarcoidosis. Sarcoidosis (a lung disease) and beryllium exposure cause similar changes in the lungs.

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***How Has  
the BeLPT  
Been Used  
in the  
Past?***

The BeLPT is used at Brush Wellman (Elmore) and other workplaces that process or machine beryllium. The test is used to find out whether workers have been sensitized to beryllium. In this situation, the testing is usually repeated every year or two.

The BeLPT has been used in community settings only a few times. ATSDR was recently involved in testing former workers, household contacts, and residents at another site where beryllium was used. The accuracy under these conditions may be slightly different than in the workplace.

Doctors use this test to find out if persons who appear to have sarcoidosis may actually have chronic beryllium disease (CBD).

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***About  
Beryllium  
Sensitivity  
(BeS)***

BeS, is an immune system response to beryllium exposure. A person can develop beryllium sensitivity soon after exposure or years later. People who are sensitized may, or may not, develop a beryllium related disease. Most doctors who treat patients with BeS advise those patients to avoid more exposure to beryllium.

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(Appendix C continued)

***Chronic  
Beryllium  
Disease  
(CBD)***

CBD develops in some sensitized people who breathe air with low levels of beryllium. CBD may be present when beryllium sensitivity is found or may develop years later. People who have CBD have damage to their lungs. Some symptoms of CBD are cough, shortness of breath, fatigue, fever, night sweats, appetite loss, and weight loss.

***What Will  
the BeLPT  
Results  
Show?***

The test should indicate whether or not you are sensitized to beryllium. It does not indicate if you have disease. If you are sensitized to beryllium you may, or may not, develop lung disease.

If you are sensitized to beryllium, you should see a doctor who specializes in lung disease. If you see a doctor for further tests, you or your insurer will have to pay for all costs.

The test has well known limitations. It does not always identify everyone who is sensitized and occasionally may identify as sensitized someone who is not.

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***Advantages  
of the Test***

If the test indicates you are not sensitized you may be reassured that your risk of developing CBD is very low. If you have BeS, you can take steps that may reduce your risk for CBD.

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***BeS, CBD,  
and  
Sarcoidosis***

BeS means that beryllium sensitivity is present, but the lungs are not damaged.

CBD means that beryllium sensitivity *and* lung damage (scars) are present. The symptoms and progression of the disease (CBD) can be managed, but there is no cure for CBD at this time.

Sarcoidosis is very similar to CBD, but beryllium sensitivity is not present. If your current diagnosis is *sarcoidosis*, *an abnormal blood test may* help your doctor to diagnose CBD. Your doctor can plan your treatment better with a more accurate diagnosis.

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***For More  
Information***

If you would like to speak to someone regarding this testing program, or if you would like to request a test, please call 1-866-577-4258 between the hours of 8 am - 8 pm (EST), Monday through Friday from May 1, 2006 through May 31, 2006. ATSDR has resources to test up to 200 people that may benefit from the testing.

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## **Appendix D.1 Informed consent with Sarcoidosis**

Flesch-Kincaid Grade Level = 7.8

### **TESTING FOR IMMUNE SENSITIVITY TO BERYLLIUM**

#### **1. Project Description**

This testing is sponsored by the Agency for Toxic Substances and Disease Registry. You have asked to be tested for beryllium sensitization.

When people are exposed to beryllium, some can develop a disease called chronic beryllium disease (CBD). You are eligible to be tested because a doctor has told you that you have **sarcoidosis**, an illness that is similar to beryllium disease. Also, you live in an area where beryllium is processed and machined.

#### **2. Procedures**

We will take about 2 tablespoons of blood from the vein in your arm. We will need less than 10 minutes to take the blood sample. We will send your blood to a lab. The lab will test your blood for sensitivity to beryllium.

We will send you a letter telling you your test results. If your blood test is abnormal or borderline, we will contact you to offer confirmatory tests. We may also call you to discuss your results, your exposure history, and your illness. You do not have to speak with us.

#### **3. Discomfort and Risks**

We expect the risks to you to be very low. You may feel a slight sting or “pinch” in your arm when the blood is drawn. You may also get a small bruise where the needle went in. Some people faint, but this is rare.

It is possible that the results from these tests might cause your doctor to want you to have more tests. If this happens you (or your insurer, Medicare, or Medicaid) will be responsible for the costs of any other tests. Before you agree to have other tests, you should discuss the risks, benefits, and alternatives with your physician.

#### **4. Benefits**

The results of this testing for Beryllium sensitivity will allow you and your doctor to better understand your health condition. The results of the test may help you and your doctor to make better decisions about your medical treatment.

If you want we will also tell your doctor what we find. We can not make or change any diagnoses, but the results might lead your doctor to make or change a diagnosis.

#### **5. Confidentiality**

Your answers and test results will be kept private to the extent allowed by law. To protect your privacy, we will keep the records under a code number rather than by name. We will keep the records in locked files and only staff associated with the testing will be allowed to see them.

#### **6. Costs**

There are no costs to you for this testing.

Based on your blood test, we might recommend that you see your doctor or a lung specialist. If you see your doctor to discuss the results of the tests, you, your insurer, Medicare, or Medicaid will need to pay your doctor.

#### **7. Persons to Contact**

If you have any questions about the testing, or if you think that you have been harmed by the testing, contact Dr. Dan Middleton. He is at the Agency for Toxic Substances and Disease Registry in Atlanta, GA. He can be reached at 404-498-0565.

## 8. Consent for Adult Participants

### ☐ **Adult Consent (18 and older)**

**I give consent** for my blood sample to be collected and tested as described in this consent form.

Please check "YES" or "NO"    ☐ YES    ☐ NO

**I give consent** for the project personnel to contact me in the future to discuss my results, my illness, and my exposure history.

Please check "YES" or "NO"    ☐ YES    ☐ NO

**I give consent** for the ATSDR project personnel to contact my private physician(s) to discuss my test results and any clinical findings related to my lungs.

Please check "YES" or "NO"    ☐ YES    ☐ NO

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Print name: \_\_\_\_\_

## **Appendix D.2 Informed Consent w/o Sarcoidosis**

Flesch-Kincaid Grade Level = 7.4

### **TESTING FOR IMMUNE SENSITIVITY TO BERYLLIUM**

#### **1. Project Description**

This testing is sponsored by the Agency for Toxic Substances and Disease Registry. You have asked to be tested for beryllium sensitization.

When people are exposed to beryllium, some will develop immune sensitivity to it. Some people with beryllium sensitivity can develop a disease called chronic beryllium disease (CBD).

You are eligible to be tested because you have ...

- ☐..... worked at a local machine shop that machined Be alloys;
- ☐ .... lived with someone who worked at a local machine shop that machined Be alloys,
- ☐ .... lived with someone who worked at the Brush Wellman facility in Elmore, OH.
- ☐ .....lived close to the Brush Wellman facility in Elmore, OH.

#### **2. Procedures**

We will take about 2 tablespoons of blood from the vein in your arm. We will need less than 10 minutes to take the blood sample. We will send your blood to a lab. The lab will test your blood for sensitivity to beryllium.

We will send you a letter telling you your test results. If your blood test is abnormal or borderline, we will contact you to offer confirmatory tests. We may also call you to discuss your results and your exposure history. You do not have to speak with us.



### **3. Discomfort and Risks**

We expect the risks to you to be very low. You may feel a slight sting or “pinch” in your arm when the blood is drawn. You may also get a small bruise where the needle went in. Some people faint, but this is rare.

### **4. Benefits**

Finding out if you are sensitive to beryllium may help to explain a current or future health problem. You will receive a letter with the results of your blood test. If you have any questions, you may speak with Dr. Dan Middleton, who leads this project. The letter will tell you if you need to see your doctor.

We will also tell your doctor what we find if you give us permission. We cannot make or change any diagnoses, but the results might lead your doctor to make or change a diagnosis.

### **5. Confidentiality**

Your answers and test results will be kept private to the extent allowed by law. To protect your privacy, we will keep the records under a code number rather than by name. We will keep the records in locked files and only staff associated with the testing will be allowed to see them.

### **6. Costs**

There are no costs to you for this testing. If you see your doctor to discuss the results of the test, you, your insurer, Medicare, or Medicaid will need to pay your doctor.

### **7. Persons to Contact**

If you have any questions about how the testing works or if you think that you have been harmed by the testing, contact Dr. Dan Middleton. He is at the Agency for Toxic Substances and Disease Registry in Atlanta, GA. He can be reached at 404-498-0565.

## 8. Consent for Adult Participants

### ☐ **Adult Consent (18 years of age and older)**

**I give consent** for my blood sample to be collected and tested as described in this consent form.

Please check "YES" or "NO"    ☐ YES    ☐ NO

**I give consent** for the project personnel to contact me in the future to discuss my results and my exposure history.

Please check "YES" or "NO"    ☐ YES    ☐ NO

**I give consent** for the investigators to contact my private physician(s) to discuss my test results and any clinical findings related to my lungs.

Please check "YES" or "NO"    ☐ YES    ☐ NO

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Print name: \_\_\_\_\_

## Appendix E. Release of Results to Personal Physician

### Release of information to your private doctor

If you would like us to send your results to your doctor, please fill in the name and address of your doctor and sign below.

**I would like my test results sent to the doctor whose name and address are shown below:**

**Doctor (*Please print Doctor's name*)**

Name: \_\_\_\_\_

Phone: \_\_\_\_\_(\_\_\_\_\_)\_\_\_\_\_

Mailing Address: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**Signatures:** Sign below

Adult Participant (sign): \_\_\_\_\_ Date: \_\_\_\_\_

Print name: \_\_\_\_\_

## **Appendix F.1 Letter to Participants with Normal Result**

Flesch-Kincaid Grade Level = 6.9

Date

Heading

Dear:

Thank you for taking part in testing by the Agency for Toxic Substances and Disease Registry (ATSDR). Your blood test did not show sensitivity to beryllium.

This test is not perfect. If your doctor suspects a beryllium condition, you may need to be tested again. Also, this does not mean that you cannot become sensitive to beryllium in the future.

If you have questions for me, you can call 1-888-422-8737 toll free and ask for Dr. Middleton. My direct number is 1-404-498-0565. Your doctor can also call me.

Sincerely,

Dan Middleton, MD, MPH  
Medical Officer

## **Appendix F.2 Telephone Script to report an Abnormal, Borderline, or Indeterminate Test Result**

Flesch-Kincaid Grade Level = 7.2

You recently provided a blood specimen for testing to the Agency for Toxic Substances and Disease Registry (ATSDR). Your blood was tested for sensitivity to beryllium. Your test result

***was borderline / was abnormal / was indeterminate***

We would like to repeat your blood test. You will receive a letter with your results. If you agree, we will contact you to schedule your second round of testing. As this is not your final test result, we recommend that you do not share it with persons outside your family. Do you have any questions for me?

## Appendix F.3 Letter to Report an Abnormal or Borderline Result

Flesch-Kincaid Grade Level = 5.6

Date

Heading

Dear:

Thank you for taking part in testing by the Agency for Toxic Substances and Disease Registry (ATSDR). As we discussed on the phone, your test result

***was borderline / was abnormal / was indeterminate***

As this is not your final test result, we recommend that you do not share it with persons outside your family. We would like to test your blood again.

You will also receive a letter with these results. If you agree, we will contact you to schedule your second round of testing. We will need to take about 4 tablespoons of blood for this. Your blood will be tested at two laboratories.

Do you have any questions for me? If you do, you can call 1-888-42ATSDR and ask for Dr. Middleton. My direct number is 1-404-498-0565. Your doctor can also call me.

Sincerely,

Dan Middleton, MD, MPH  
Medical Officer

## Appendix G. Script for Reporting Final Results

Page 1 of 2

*Note: this letter to be completed in accordance with the plan for interpreting results and making recommendations.*

Flesch-Kincaid Grade Level = 6.9

Thank you for taking part in testing by the Agency for Toxic Substances and Disease Registry (ATSDR). Your original blood test was interpreted as ***abnormal / borderline/indeterminate***.

We have repeated the test on a second blood specimen. Your blood was tested at two laboratories. These two test results on your most recent blood specimen were \_\_\_\_\_ and \_\_\_\_\_.

We interpret these results to mean that

- ☐ you are sensitized to beryllium.
- ☐ you may or may not be sensitized to beryllium.
- ☐ you are probably not sensitized to beryllium.

You ☐ did ☐ did not

...report having one or more of the symptoms we asked about.

We recommend that you make your doctor aware of these

- ☐ test results      ☐ and symptoms,

and,

- ☐ that you seek further evaluation by a specialist with experience diagnosing and treating beryllium disease.
- ☐ that you seek further evaluation by your family physician, who may or may not refer you to a specialist.
- ☐ that you make sure your family physician receives a copy of your test results. No specific followup is recommended.

Do you have any questions for me. You will also receive a letter with your results. If you have questions for me later, you can call 1-866-577-4258 toll free and ask for Dr. Dan Middleton. My direct number is 1-404-498-0565.

Your doctor can also call me.



## Appendix G. Letter to Report Final Results

Page 1 of 2

*Note: this letter to be completed in accordance with the plan for interpreting results and making recommendations.*

Flesch-Kincaid Grade Level = 6.9

Date

Heading

Dear:

Thank you for taking part in testing by the Agency for Toxic Substances and Disease Registry (ATSDR). Your original blood test was interpreted as ***abnormal / borderline/indeterminate***.

We have repeated the test on a second blood specimen. Your blood was tested at two laboratories. These two test results on your most recent blood specimen were \_\_\_\_\_ and \_\_\_\_\_.

We interpret these results to mean that

- ☐ you are sensitized to beryllium.
- ☐ you may or may not be sensitized to beryllium.
- ☐ you are probably not sensitized to beryllium.

You ☐ did ☐ did not

...report having one or more of the symptoms we asked about.

We recommend that you make your doctor aware of these

- ☐ test results      ☐ and symptoms,

and,

- ☐ that you seek further evaluation by a specialist with experience diagnosing and treating beryllium disease.
- ☐ that you seek further evaluation by your family physician, who may or may not refer you to a specialist.
- ☐ that you make sure your family physician receives a copy of your test results. No specific followup is recommended.

If you have questions for me, you can call 1-866-577-4258 toll free and ask for Dr. Middleton. My direct number is 1-404-498-0565.

Your doctor can also call me.

Sincerely,

Dan Middleton, MD, MPH  
Medical Officer

## **Appendix H. Laboratories to Contact for Information on Blood Collection and Shipping for the BeLPT**

### **Specialty Laboratories, Inc.**

OncQuest

2211 Michigan Avenue

Santa Monica, California 90404-3900

(310) 828-6543

(800) 421-4449

### **Website**

<http://www.specialtylabs.com/>

<http://www.specialtylabs.com/tests/details.asp?id=1470>

### **National Jewish Medical and Research Center**

Denver, Colorado 80206

phone: (303) 398-1722

### **Website**

<http://www.njc.org/>

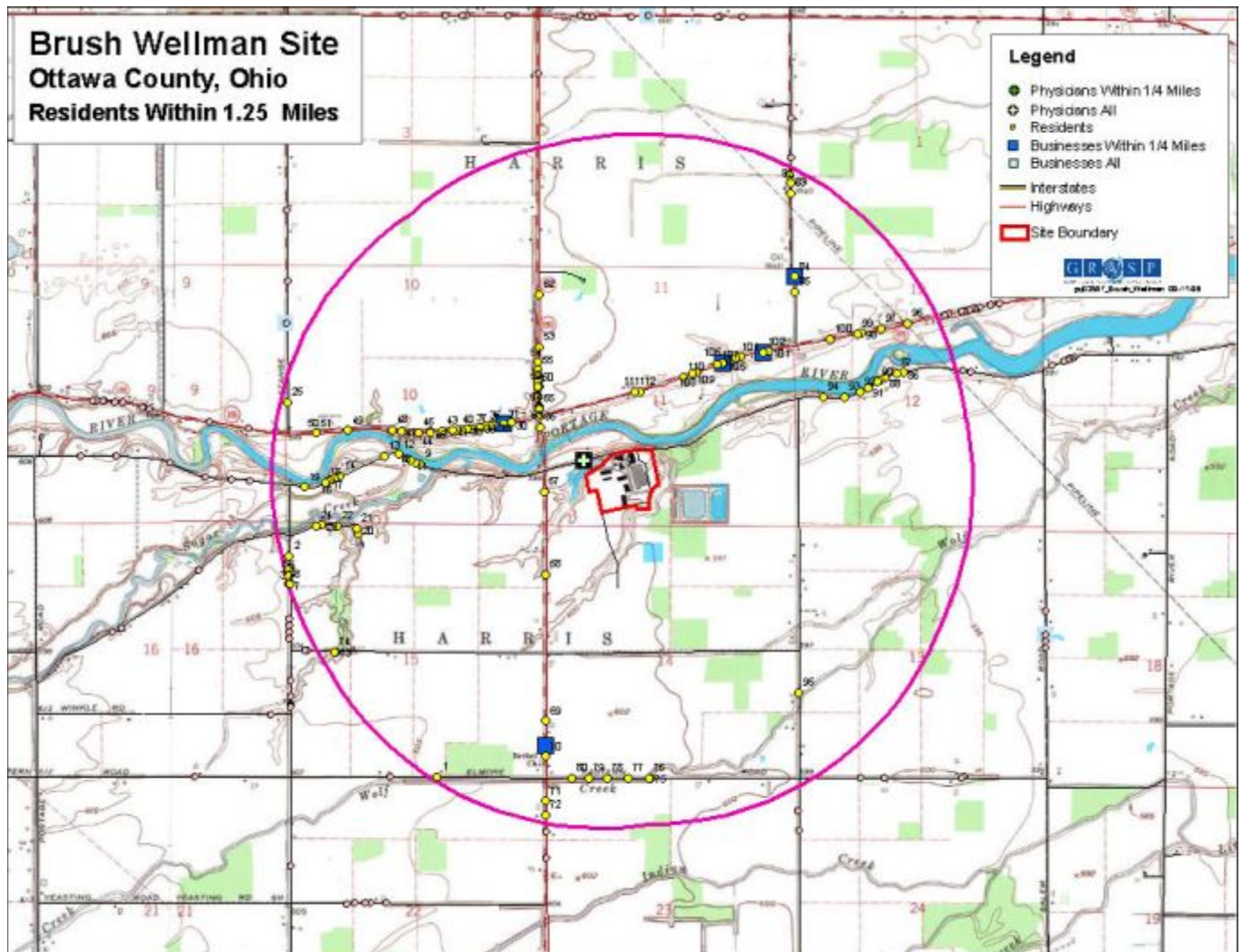
[http://www.njc.org/lab/beryllium\\_blood.html](http://www.njc.org/lab/beryllium_blood.html)

## Appendix I. Area Information

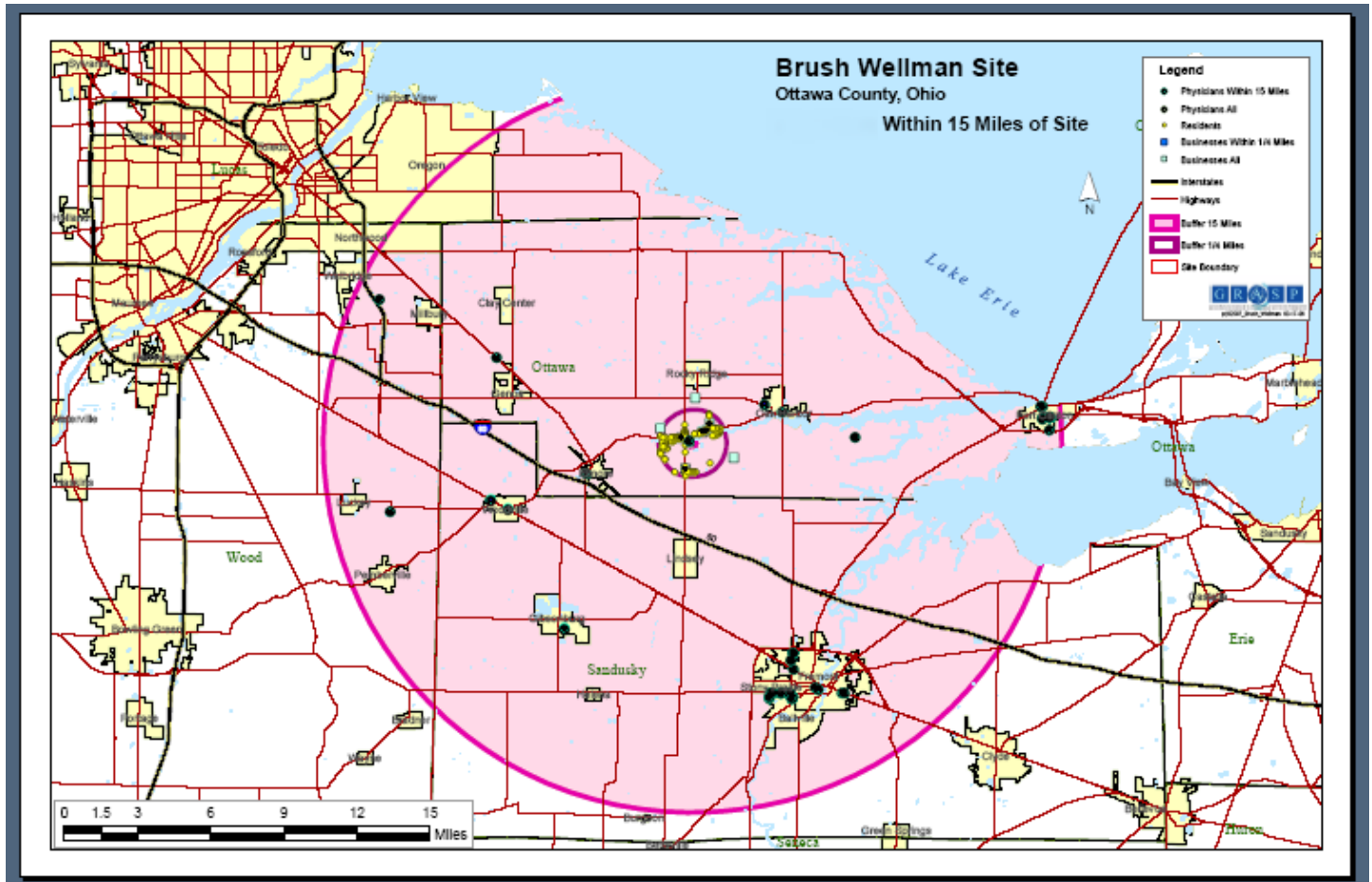
Table I.1 Demographics of residential areas, by age group			
Age Groups	Distance from facility		
	1 Mile		15 Miles
Age 65 and Older	30		13,075
Age 18 to 64	100		53,737
Age 18 and Under	40		23,450
Total Population	170		90,262

Table I.2 Machine shops that contract (or have contracted) to machine beryllium alloys			
COMPANY/ADDRESS	PHONE		STATUS
Elmore Manufacturing Co, LLC	343 Clinton, Elmore, OH		Current Machine Shop Contractor
Royal Tool & Machine Co	5740 Woodville Rd, Northwood, OH		Former Machine Shop Contractor

## Appendix J.1 Topographic Map of 1.25 mile area

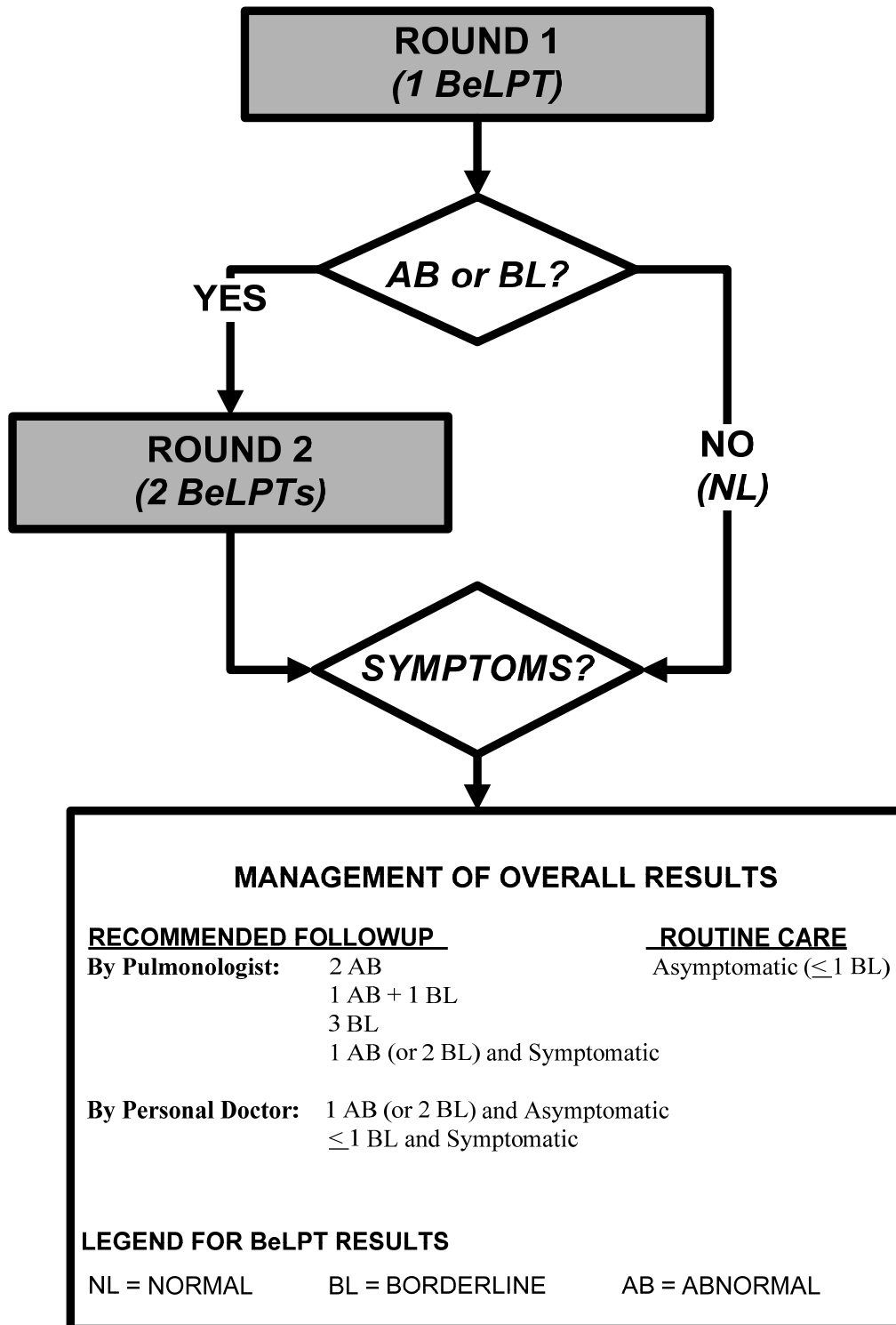


## Appendix J.2 Topographical Map of Fifteen Mile Area



Appendix K.

## Plan for Testing and Interpreting Results (Normals, Abnormals, and Borderlines)



## Appendix L. Consent Comprehension

Dear Participant,

Thank you for agreeing to have your blood tested. Before we take your blood we want to make sure you understand this program. Please take a few minutes to answer questions about this screening. When you are done, give the sheet to the interviewer. The interviewer will look at your answers and give you more information if needed.

*Select either "No", "Yes", or "Don't know"*

**1. I am taking this test because...**

A. I felt pressured to take this test. ☐No ☐Yes ☐Don't know

B. I choose freely to join take this test. ☐No ☐Yes ☐Don't know

**2. By signing the consent form...**

A. I agreed to join studies in the future. ☐No ☐Yes ☐Don't know

B. I may choose to stop participating at any time. ☐No ☐Yes ☐Don't know

**3. I was given the name and telephone number of a person I can call if I have questions about this study?**

☐No ☐Yes ☐Don't know

**4. I was asked to take part in this project because**

A. I live in an area of the country where beryllium is processed. ☐No ☐Yes ☐Don't know

B. Everyone in Ohio is being asked to be tested. ☐No ☐Yes ☐Don't know

**5. In 1-2 short sentences, describe how knowing whether you are sensitized to beryllium can help you.**

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**6. Are these statements about the testing plan are true?**

A. Someone will take blood from my arm. ☐No ☐Yes ☐Don't know

B. Brush Wellman is running this study. ☐No ☐Yes ☐Don't know

C. Someone from this project may call me later. ☐No ☐Yes ☐Don't know

D. My blood will be tested for beryllium sensitivity and other non-related chemicals. ☐No ☐Yes ☐Don't know



*Plan Revised in Response to Public Comments*

7. In 1-2 short sentences, describe why this testing (or project) is being done.

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8. As a participant in this program, I am aware there may be some risks. I was told that...

*Select either "No", "Yes", or "Don't Know"*

- A. A small number of people who give blood may faint ☐ No ☐ Yes ☐ Don't know
- B. I may get a small bruise where the needle was inserted ☐ No ☐ Yes ☐ Don't know
- C. My doctor may ask me to have more medical tests based on the results of this test ☐ No ☐ Yes ☐ Don't know
- D. If my doctor recommends medical tests, my insurance or I would be responsible for the cost. ☐ No ☐ Yes ☐ Don't know
- E. Your answers and test results will be kept private to the extent allowed by law. This means a judge could order all study information including who took part in this study be handed over to a court of law. ☐ No ☐ Yes ☐ Don't know

9. To identify which tube has my blood in it,  
the researchers will write my name on the tube. ☐ No ☐ Yes ☐ Don't know

10. My name or other identifying information will be used  
when presenting the test results to the public. ☐ No ☐ Yes ☐ Don't know

11. I understand that the test may need to be repeated. ☐ No ☐ Yes ☐ Don't know

**Please hand this sheet back to the interviewer.**